

Why you should consider

# THE PACEY CUFF



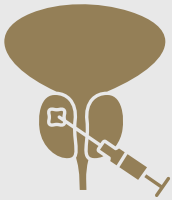
## A MALE INCONTINENCE DEVICE

The Pacey Cuff is a male urethral control device that helps with urinary incontinence. It can be worn all day and restricts urine flow while allowing blood flow. The device fits the male anatomy, as the major vein and artery are on the dorsal surface and the urethra is on the ventral surface. It avoids the problems seen with clamps, such as blood flow occlusion and irritation.

## VALUE

- Can be worn 24 hours.
- Do not restrict blood flow.
- Lightweight and discrete.
- Can be use after Prostatectomy.

## WHEN TO USE THE PACEY CUFF



### Post-Prostatectomy \*

Post -Prostatectomy Patients , with no suspicion of anastomotic failure who have had catheter removal and no infection indicators, can use the Pacey Cuff.



### Radiotherapy

When treating prostate cancer with radiation therapy, it is preferred to have a full bladder. The Pacey Cuff is a cost-effective external solution that helps maintain a full bladder and prevent leakage.



### AUS Artificial Sphincters

In addition to being compatible with all artificial urinary sphincter (AUS) devices, the Pacey Cuff is Highly recommended because it has been demonstrated to extend the lifespan of the AUS.

## CIRCULATION PROTECTION TESTING METHODS



100%

### Vascular Surgery Doppler Ultrasound

These tests show that in the presence of normal circulation the Pacey Cuff Device can occlude the urethra and be protective of blood flow.



100%

Urinary control

### Pulse Oximetry

Results from a Pulse Oximetry study on the Pacey Cuff :  
Pulse: 76.  
SPO2 98.



3-5 sec.

### Capillary refilling time:

Return of color and blood in 3-5 seconds in the head of the penis with compression released.

\*Go to the last page for the entire Post-Prostatectomy Rapoport Protocol

# THE PACEY CUFF



**PACEY CUFF™**  
URETHRAL CONTROL DEVICE



## SAFETY EFFICACY CLINICAL STUDY SUMMARY

Jula A. , Logadottir Y. , Olsen Ekerhult T., Sahlgrenska Academy, Institute of clinical sciences, Dept. of Urology, Gothenburg, Sweden – May 2020 .

A prospective pilot study included patients with urinary leakage and penile clamps with a circumference of 4-6 cm (small), 7-9 cm (medium) and >10cm (large). Inclusion criteria consisted of good hand function, a full cognitive function and a minimum length of 3 cm and a circumference of 5 cm of the penis.

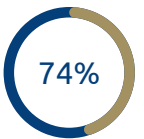
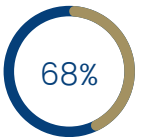
The first visit consisted of information and evaluation of the patient, collection of incontinence pads and measurement of the penis. Instruction on how to use the clamp, in two hours intervals and during the night.

## CONCLUSIONS

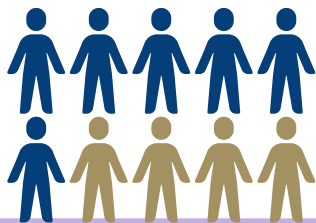
The penile clamp shows promising results reducing leakage with minimal risks of complications. Quality of life is improved, even with persistent leakage when not using the clamp. The penile clamp is a good treatment for patients unsuitable for incontinence surgery. However, patient selection is of utter importance regarding hand and cognitive function as well as the anatomy of the penis.

## RESULTS OF THE STUDY

- The results showed a median reduction of urinary leakage .
- Patients found it comfortable to use.
- Patients would recommend the clamp to others with a similar problem.



## THE PACEY CUFF IN FACTS



**6,000+**

Patients successfully used the Pacey Cuff.

## JOULE INNOVATIONS AWARD



The Pacey Cuff as a winner as urethral control device Innovation.

## SERIOUS ADVERSE EVENTS

**0%**

Our medical device has had over **15,000** units sold and zero serious adverse events reported.

# CHOOSE THE RIGHT SIZE



## Pacey Cuff Sizing Chart

### Circumference

If your measurement falls between two sizes, we recommend choosing the larger.

	Centimeters	Inches
Small	3 - 7 cm	1 - 2.75"
Medium	7 - 11 cm	2.75 - 4"
Large	11 - 14 cm	4 - 5.5"

### Length

This number indicates the minimum length required to secure the it in place.

	Centimeters	Inches
Small	3 cm	1.25"
Medium	4 cm	1.75"
Large	5 cm	2"

Choosing the correct size is essential for a successful performance

## HOW TO APPLY THE PACEY CUFF



### STEP 1

Apply the Power Sleeve to the mid-shaft of the penis and secure the Velcro fastener.

The Power Sleeve of the penis clamp should be snug, but not tight.



### STEP 2

Apply the Pacey Cuff over the end of the penis, and center it over the Power Sleeve.

Be sure to center the urethral compressor under the urethra.



### STEP 3

Secure the Pacey Cuff by compressing the top and bottom parts with the Velcro strap and note the number.

Check for any pinching or leaking and double-check the top and bottom parts are still centered on your penis.



**PACEY CUFF™**  
URETHRAL CONTROL DEVICE

# POST-PROSTATECTOMY PROTOCOL

Post-operative Rapoport Protocol  
Dr. Daniel Rapoport, M.D. (Br. Col.), FRCSC – Urology,  
Department of Medicine, UBC.

## Protocol Indications for the Pacey Cuff use

Post -Prostatectomy patients with no suspicion of anastomotic failure who have had catheter removal and no infection indicators, who have incontinence demonstrated, and who have had authorization from surgeon, can use the Pacey Cuff. Pacey Cuff is used until incontinence resolves to reduce absorptive pad use by patient. Patient leakage control increases self- esteem and mobility by giving the patient a tool to apply at will.

## Catheter Removal Post-Prostatectomy

Your Foley catheter should be removed approximately 10 days from the day of surgery. On the day you are going to have your catheter removed, drink plenty of fluids before you arrive at the office.

The purpose of the visit is to ensure you can urinate with a strong stream following catheter removal; the recovery of total urinary control will come later. The return of sphincter control after catheter removal occurs:

- 1st at night.
- 2nd when sitting.
- 3rd when ambulating.

## Wound Healing

Most of the healing occurs in the first 6-8 weeks after surgery. Then the Pacey Cuff becomes an option.



Use the Pacey Cuff post-operation with Urologists agreement. Delay of 3+ weeks after catheter removal is suggested.

## Contraindications

- Use of the Pacey Cuff too early might interfere with progress of return of voluntary bladder control.
- Do not use the Pacey Cuff if infection is present.
- The Pacey Cuff should not be used at night during this period.
- The Pacey Cuff should not be used continuously but for periods of mobility when high leakage and soiling of clothing is a risk.
- Do not use it if the patient has regained continence.

## Recommendations

Recommend use of the Pelvic Exercises for the patient using the cuff. Encourage patient mobility during the recovery period for general fitness. Then use of the Pacey Cuff should be reduced progressively as sphincter control is regained. Pad use should continue when using the Pacey Cuff.

