



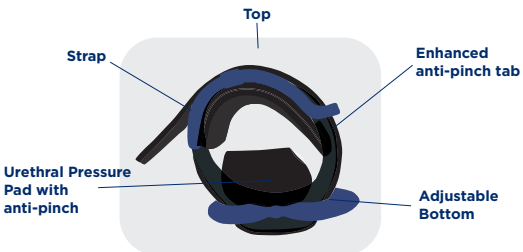
PACEY CUFF™

INDICATIONS FOR USE

The Pacey Cuff Ultra is indicated for provision of male urinary continence. The device is used during waking hours as required. A light pad is recommended for use with the device.

COMPONENTS

Pacey Cuff - Urethral control device designed to stop leaks without restricting circulation.



Power Sleeve - Designed for use with the Pacey Cuff urethral control device.



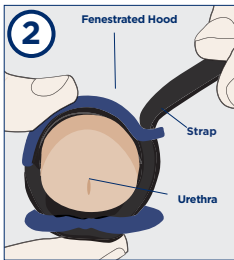
INSTRUCTIONS FOR USE



1. Attach the Power Sleeve

- Wrap the Power Sleeve mid-shaft around the penis before applying the Cuff.
- Attach the ends together. The sleeve should be snug.
- The ends should be attached on the side of the penis. If there is discomfort, re-apply less tightly.
- Apply the Pacey Cuff over top of the Power Sleeve

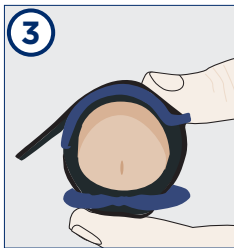
Important: Do not over-stretch the Power Sleeve.



2. Position Pacey Cuff

- Squeeze the top and bottom pieces together, around the penis, with your dominant hand to obtain necessary compression to stop the flow of urine.

Important: Do not use the strap guide to compress the Pacey Cuff.

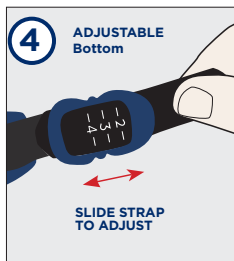


3. Secure Pacey Cuff

- Secure the remaining strap.
- Ensure top hood and bottom pressure pad are centered on the penis. Inspect and prevent any skin pinching that may have occurred between upper and lower parts.

Important: Compression and tightening the Velcro® strap may need to be attempted a few times to determine the correct pressure.

If leaking persists:



In addition to the top strap, **the bottom piece can be adjusted** to the left or right to adjust the overall fit.

If leaking occurs after first application:

1. The bottom strap setting should arrive set at around 3.
2. Slide the bottom strap to a higher setting (3.5-4).

Recommended:

- Use brief-style, form-fitting undergarments rather than looser boxer shorts.
- Petroleum gel may be used to protect the skin from possible irritation.
- The device may be worn during exercise and swimming.

Cleaning:

Wash the Pacey Cuff Ultra and the Power Sleeve in warm water. A mild soap free of any hydrating agents, perfumes, deodorants, preservatives, detergents or coloring may be used. Do not tumble dry.

Voiding:

- The Power Sleeve does not need to be removed during urination. When voiding, simply loosen the Pacey Cuff, and re-tighten the Cuff once the bladder is empty.
- Void every 1-2 hours and exercise light fluid intake.

Product life cycle:










Pacey Medtech recommends that the device be replaced as required (approximately every 6 months).

Warnings: 

- Remove the Pacey Cuff if pain, swelling, bleeding or discomfort occurs.
- If patient has special needs, use the device with professional supervision.
- Do not use the device if you are on medication that impairs your ability.
- If skin becomes irritated, discontinue use until the irritation resolves.
- Mechanical forces that twist or alter the Pacey Cuff position may cause pain. If this occurs, remove the Pacey Cuff and let blood supply return. If pain does not subside, consult your medical professional.
- **The Power Sleeve is not MR Compatible.**

Consult a medical professional if the following conditions are present:

- Conditions causing abnormal blood clotting. Conditions that impair blood clotting and conditions that clot blood such as coagulopathy. Increased blood clotting may be congenital and/or acquired.
- Drugs that impair pain recognition (e.g. narcotics and sleeping medication).
- Drugs that impair clotting and drugs that increase clotting.
- Conditions such as sickle-cell disease that cause slow blood flow and clot formation.
- For serious medical conditions please consult your medical professional.
- For advanced peripheral or cardiac vascular disease or diabetes mellitus, consult your physician or medical professional prior to use.
- If you have a urinary tract infection (UTI), consult your physician or medical professional before use.

Symbol	Definition
	Manufacturer
	Authorized representative in the European Community
	Consult instructions for use
	Batch code
	CE Mark
	Product code
	MR Unsafe (Power Sleeve only)
	Warnings
	Medical Device



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