Instruction for Use

Penile Clamp

Device Description

The Penile Clamps are provided for use in Urology procedures. Penile Clamp is an external medical device used to control male urine leakage by compressing the urethra and preventing the flow of urine. The configuration available include:

Family	Types	Length (Cm)	Width (Cm)
Penile Clamp (PC)	Clip Type	6	2
	Velcro Type		

Intended Purpose

Penile Clamp is a device used to prevent or reduce episodes of male urinary incontinence.

Intended User

This device should be administered to humans only by physicians authorized by the Competent Authority of the country in which the physician is practicing.

Medical Conditions to be Treated

- Male urinary incontinence
- Post-prostate surgery urinary leakage
- Stress urinary incontinence in men requiring non-invasive external management

Performance Characteristics of the device

Penile Clamps are used in men to treat incontinence. These incontinence Clamps are placed around the penis to prevent urine leakage. Penile Clamp are safe non-invasive procedures for the treatment of Male Incontinence and has an external clamp used for gently applying pressure to stop urine flow through urethra.

Indications

- Penile Clamps is used in male adults to treat the following:
  - Urinary Incontinence in men
  - After Prostate Surgery.
- Penile Clamp is used in men to manage the urine leakage after prostate surgery.

Contraindications

- Penile Clamps are not recommended for men with storage lower urinary tract symptoms (LUTS).
- The use of this device in patients with severe spinal cord injuries and severe mental disability is not recommended.
- Not recommended in individuals with latex allergy.
- Not recommended in case of wound or swelling at the site of application.

Precautions & Warnings

Carefully read all instructions for use and product labelling. The device shall only be applied for its intended use and in accordance with these instructions. Observe all cautions and warnings throughout these instructions. Failure to do so may result in complications.

Precaution:

- All medical staff is responsible for using the appropriate technique and deciding on the indication for use of this device based on own experience, training and medical judgment.
- Store in a dry, cool place. Avoid extended exposure to sun light.
- If any component is found damaged or unsuitable for use, do not use. Contact" Distributor" for replacement.

Warnings:

- Do not keep it clamped for more than 2 hours in the same place. Clamps must be released every 2–4 hours to empty the bladder. Allowing urine to remain in the bladder for prolonged periods increases the risk of urinary tract infections. Do not use a clamp in conjunction with other incontinence devices (except absorbent pads), with indwelling catheters, or with implanted penile prostheses.
- Contact your doctor immediately if any swelling, bruising, discoloration (change in colour), or sores develop on the penis while using the clamp. In many cases some simple adjustments and additional practice using the clamp will alleviate the problem.
- Do not use near open sores. After sores are completely healed, the clamp may be used again. Patients with altered mental status should not be allowed to wear a clamp. Do not hesitate to contact your physician if you have any concerns or questions about using a clamp.
- Do not use the clamp at night while sleeping.

Intended Patient Population

- The device is intended for use in adult male patients having the above-mentioned conditions.

Shelf-life

Penile Clamp is a non-sterile device, hence there is no specific shelf life for the product.

Sterility

- The Penile Clamps are supplied non-sterile and can be re-used.
- The Penile Clamps are packed single.

Directions for Use

Suggested instructions for using Penile Clamps:

- Open the package at the Chevron Side ('V' Notch) of the pouch.
- Open the clamp and place it around the penis about halfway down the shaft. The hump side of the clamp is placed on the underside of penis. The clamp flexes to fit comfortably over penis. Then squeeze the clamp shut, making sure it is not too tight.
- To release the catch, press inward on both the spring wire loops. Make sure the clamp is not so tight that it stops blood circulation.
- Contact doctor in case if you have:
  - Trouble removing the clamp
  - Swelling, discolouration or discharge from the penis
  - Skin irritation
  - Loss of feeling in penis
  - Pain or irritation on penis
  - Any other unusual symptoms

Instruction for Use

Penile Clamp

Cleaning Instructions

Follow the steps below to clean the Clamp. The clamp must be cleaned after each use.

- Wash the clamp in a sink with mild soap and warm water. Do not use bleach, detergent or hot water on the clamp.
- Rinse the clamp thoroughly in cool, clean water.
- Gently squeeze the foam to get rid of excess water.
- Let the clamp dry in a cool place away from excess heat or direct sunlight. Do not put your clamp in the washer or dryer, or use a blow dryer on it.

Disposal Instructions

- Dispose of all equipment in appropriate containers. Handle and dispose of in accordance with accepted medical practice and applicable local, state and federal laws and regulations.

Explanation of symbols used on label

Symbol	Title of Symbol	Symbol	Title of Symbol	Symbol	Title of Symbol	Symbol	Title of Symbol	Symbol	Title of Symbol
REF	Catalogue Number	UDI	Unique Device Identifier		Do not re sterilize		Country of Manufacture	MD	Medical Device
	Manufacturer		Date of manufacture		Keep Dry		Caution		Single Sterile barrier system with protective packaging inside
LOT	Batch Code		Use by Date		Keep Away from Sunlight		Do not re-use	75% 30%	Humidity Limit
STERILE EO	Sterilized using ethylene oxide		Consult Instructions for Use	35 °C 12 °C	Temperature Limit		Do Not Use if Package is Damaged		

Aster Medispro Pvt.Ltd
S.P.181, 10th Main, 1st Stage,
Dr. B.R. Ambedkar Industrial Estate (KSSIDC)
Jigani Industrial Area, Jigani,
Bangalore- 560105, Karnataka, India.
Tel:+91 80-2979550
Email:info@astermedispor.net
Web:www.astermedispor.net

Bibliography

- Summary of safety and effectiveness -Uromed Alternative Bladder Control Continence Device. https://www.accessdata.fda.gov/cdrh_docs/pdf/K971992.pdf
- The Simon foundation for Continence https://simonfoundation.org/penile-clamp-urinary-incontinence/
- EN ISO 15223-1:2021-Medical Devices-Symbols to be used with information to be supplied by the manufacturer-Part 1: General Requirements
- EN ISO 20417:2021 Medical Devices-Information to be supplied by the manufacturer